

REMARKS

Claims 58-90 are pending in the application. Both of the independent claims (claims 58 and 82) have been amended by this Reply. No new matter has been added.

Remarks Concerning 37 C.F.R. § 1.98(a)(3) and MPEP § 609

On page 2 of the December 21, 2004 Office Action, the Examiner stated that the Information Disclosure Statement and supplements thereto submitted by Applicants do not comply with the C.F.R. § 1.98(a)(3) requirement that a statement of the relevance of a foreign-language reference be provided when such a reference is included in the Information Disclosure Statement. Applicants acknowledge that several foreign-language references were included in the Information Disclosure Statement and supplements thereto. These foreign language references were submitted, not because of any known applicability, but only based on general knowledge that such references may be material to patentability.

Also on page 2 of the December 21, 2004 Office Action, the Examiner encourages Applicants, pursuant to MPEP § 609, to provide a “concise explanation of why the English language information is being submitted and how it is understood to be relevant.” In compliance with those requests from the Examiner, Applicants have now prepared a Statement of Pertinent References, which has previously been submitted to the Examiner. A copy of this submission is attached hereto. Applicants believe that the Statement of Pertinent References should alleviate the Examiner's concerns.

Remarks Concerning Rejections Under 35 U.S.C. §103

In the December 21, 2004 Office Action, the Examiner did not reject any of the claims under 35 U.S.C. § 102. Applicants thus turn to the rejections under 35 U.S.C. § 103.

On page 2 of the December 21, 2004 Office Action, the Examiner rejected claims 58-90 as being unpatentable over U.S. Patent No. 6,233,525 B1 to Langley et al. ("Langley") in view of U.S. Patent No. 5,781,442 to Engleson et al. ("Engleson"), in further view of U.S. Patent No.

6,451,203 B2 to Brown ("Brown"), and in still further view of U.S. Patent No. 5,132,026 to Baluyot ("Baluyot"). Applicants respectfully traverse that rejection.

The Examiner cited all of the aforementioned references in rejecting all of the pending claims 58-90. However, the Examiner cited only Langley in view of Brown in rejecting the two independent claims, 58 and 82. In light of the amendments made herein to those two claims, Applicants will distinguish those two claims over Langley in view of Brown, rendering the Examiner's arguments moot with respect to the dependent claims.

Claims 58 and 82 of the present application are directed to a system for monitoring a portion of a blood component collection procedure in a blood collection facility, including a system server for monitoring a blood collection component collection instrument ("the instrument") during *and throughout* the operation of the instrument.

Specifically, Claim 58 requires a "system server being operably connected to the blood component collection instrument during *and throughout* the operation of the blood component collection instrument" (emphasis added). Likewise, Claim 82 calls for a computer-readable medium for use in an operator interface for monitoring a blood component collection procedure, wherein a segment of the medium is for "reading information from a blood component collection instrument during *and throughout* the operation of the blood component collection instrument" (emphasis added).

None of the references cited by the Examiner, either alone or in combination, discloses either a server for monitoring the instrument during and throughout the operation of the instrument, as in claim 58, or a segment for reading information from the instrument during and throughout the operation of the instrument, as in claim 82. Langley relates to a blood component collection optimization system. A blood component collection procedure is optimized based on a set of process parameters, and the collection procedure is performed based on the optimized parameters. Langley does not disclose monitoring the instrument during the blood collection procedure; Langley discloses only transmitting the parameters to the collection device. As the Examiner observed, Langley discloses that those parameters may be transmitted to the device during the blood collection procedure (col. 13, ll. 40-44). However, as the Examiner also observed on page 13 of the December 21, 2004 Office Action, Langley does not disclose *monitoring or reading information from* the instrument during the collection procedure.

Brown fails to cure the deficiencies of Langley. Brown relates to a system and method for separating whole blood into red blood cells and plasma within a rotating centrifugal separation device. The system includes an "instrument manager" for communicating "with low level peripheral controllers" (col. 7, ll. 21-23). The instrument manager also "conveys back to the application control manager status data about the operational and functional conditions of the processing procedure" (col. 7, ll. 36-39). However, Brown differs from the present application in two significant respects. First, Brown is an entirely self-contained system for the separation of blood into red cell and plasma components; there is no server in Brown, much less a server that monitors a blood *collection* procedure. Second, Brown does not disclose monitoring a blood collection procedure *throughout* the procedure, as the independent claims (as amended) of the instant application now require.

Applicants therefore submit that the combined teachings of Langley and Brown do not satisfy the independent claims of the present application. Specifically, neither of those references, either alone or in combination, discloses a server that monitors a blood collection procedure during and throughout the entirety of the procedure.

In addition to failing to disclose each of the limitations of the independent claims of the present application, the combination of Langley and Brown is improper because there is no motivation or incentive in the prior art to combine those references in the manner suggested by the Examiner (In re Napier, (Fed. Cir. 1995), 55 F.3d 610, 613). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the prior art (In re Fine, (Fed. Cir. 1988), 837 F.2d 1071, 5 USPQ2d 1596; In re Jones, (Fed. Cir. 1992), 958 F.2d 347, 21 USPQ2d 1941).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combinations and the reasonable expectation of success must

both be found in the prior art, not in the applicant's disclosure (In re Vaeck, (Fed. Cir. 1991), 947 F.2d 488, 20 USPQ2d 1438). The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness (MPEP § 2142). In the present case, the Examiner has failed to meet that burden.

Langley is from the networked blood collection field, as is the present application, with an emphasis on optimizing the procedure using process parameters. Brown, on the other hand, discusses a way to use a self-contained centrifuge system for separating already-collected blood into different components. On page 14 of the December 21, 2004 Office Action, the Examiner stated that it would have been obvious to combine Langley and Brown because Langley "collects blood and would require process monitoring [from Brown] to enable the optimizer of Langley to perform its function." However, the Langley disclosure indicates that its disclosed system is already capable of performing the optimizing function, without the process monitoring disclosed by Brown. The Examiner's suggestion to combine Langley and Brown is therefore not disclosed in either Langley or Brown. Neither of those references, nor any other prior art in either of those fields, includes any suggestion that the system provided by Langley would be helpful, advantageous or operative if combined with Brown as suggested by the Examiner. Moreover, the Examiner's proposed impetus for combining Langley and Brown would render redundant the optimization process of Langley. As a result, there is no showing of any motivation to combine the references.

Instead, it appears that the Examiner used hindsight in making the suggested combination. However, hindsight combination of references, using the present invention as a roadmap, is improper. It is well recognized that the claimed invention cannot be used as an instruction manual or template to piece together the teachings of the prior art in an attempt to render the claimed invention obvious (In re Fritch, (Fed. Cir. 1991), 972 F.2d 1260, 1266). Most importantly, and as previously stated, neither Langley nor Brown discloses monitoring a blood collection instrument during and *throughout* the entirety of the blood collection procedure, as do the amended independent claims of the present application.

On pages 5-13 of the December 21, 2004 Office Action, the Examiner rejected certain dependent claims as being unpatentable over the combined teachings of Langley, Brown, Engleson and Baluyot, namely claims 59-81 and 83-90. Because the independent claims are all

distinguishable over those references for the reasons stated above, and further because there is no motivation to combine those references, the dependent claims of the application are therefore distinguished over those references as well.

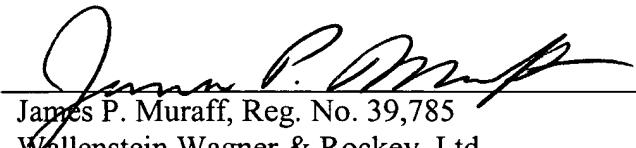
Applicants therefore respectfully request that the § 103 rejection be withdrawn.

CONCLUSION

In light of the amendments made to the independent claims, and the remarks made herein, Applicants submit that Claims 58-90 are in condition for allowance. Applicants respectfully request the Examiner to withdraw the rejections and allow the claims to issue. If it may be of assistance to contact the Applicants regarding the present application, the Examiner is invited to do so. The Commissioner is authorized to charge Deposit Account No. 23-0280 in connection with any fees associated herewith.

Respectfully submitted,

Dated: April 8, 2005

By: 

James P. Muraff, Reg. No. 39,785
Wallenstein Wagner & Rockey, Ltd.
311 South Wacker Drive, 53rd Floor
Chicago, Illinois 60606-6630
312.554.3300

CERTIFICATE UNDER 37 C.F.R. § 1.10

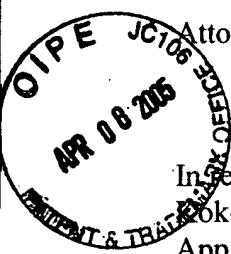
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Gillian Gardner/222702

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Attorney Docket No. F-5728 (1417P P 591)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:
Eok-Hwee Ng et al.
Application No.: 09/865,196
Confirmation No.: 2014
Filed On: May 24, 2001

Examiner: Shapiro, Jeffrey A.
Art Unit: 3653

For: System and Method for Managing Inventory of
Blood Component Collection Soft Goods in a
Blood Component Collection Facility

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**IDENTIFICATION OF PERTINENT REFERENCES FROM
PREVIOUSLY FILED INFORMATION DISCLOSURE STATEMENTS**

Dear Sir:

This filing is in response to a request by the Examiner in paragraphs 1 and 2 of the Office Action dated December 21, 2004 regarding foreign references and the number of references previously filed by Applicants within Information Disclosure Statements for the present application.

Specifically, in response to 37 CFR 1.98(a)(3), Applicants previously submitted references after becoming aware of such references. Applicants do not have a translation of the foreign language references. Therefore, Applicants are unable to provide a concise statement describing the references, as requested. Applicants have only provided such references because, from the abstracts of such references, when available, Applicants believed that such references could be material to patentability, although Applicants are not certain that such references are in fact material. However, the following may assist in the Examiner's review of the present application.

Specifically, pursuant to MPEP Section 2004, paragraph 13, Applicants believe that the references listed below may be more pertinent for the examination of the present application. MPEP 2004, paragraph 13 suggests that Applicants identify the more pertinent references when many references have been cited in one or more Information Disclosure Statements.

U.S. PATENT DOCUMENTS

Document No. Kind Code (if known)	Name of Patentee or Applicant	Publication Date (MM-DD-YYYY)
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4,464,172	Lichtenstein	08/07/1984
4,476,381	Rubin	10/09/1984
4,657,529	Prince et al.	04/14/1987
4,810,090	Boucher et al.	03/07/1989
4,810,090	Boucher et al.	03/07/1989
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4,851,126	Schoendorfer	07/25/1989
4,898,576	Philip	02/06/1990
4,922,922	Pollock et al.	05/08/1990
4,968,295	Neumann	11/06/1990
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5,178,603	Prince	01/12/1993
5,273,517	Barone et al.	12/28/1993
5,311,908	Barone et al.	05/17/1994
5,392,209	Eason et al.	02/21/1995
5,421,812	Langley et al.	06/06/1995
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5,437,624	Langley	08/01/1995
5,496,265	Langley et al.	03/05/1996
5,496,301	Hlavinka et al.	03/05/1996
5,514,095	Brightbill et al.	05/07/1996

5,637,082	Pages et al.	06/10/1997
5,643,193	Papillon et al.	07/01/1997
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5,812,419	Chupp et al.	09/22/1998
5,813,972	Nazarian et al.	09/29/1998
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6,055,487	Pang et al.	04/25/2000
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Foreign Patent Document			Name of Patentee or Applicant	Date of Publication
Office	Number	Kind		
AU	685,495		Cobe Laboratories, Inc.	05/11/1995
CA	2,133,913		Cobe Laboratories, Inc.	04/22/1995
EP	0 192 786	B1	Medrad, Inc.	09/03/1986
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EP	0 580 299	A1	Cobe Laboratories, Inc.	01/26/1994
PCT	WO 89/08264	A1	Ballies	09/08/1989
PCT	WO 94/11838	A1	Abbott Laboratories	05/26/1994
PCT	WO 97/41525	A1	Hunter Area Pathology Service	11/06/1997
PCT	WO 99/04043	A1	Abbott Laboratories	01/28/1999
PCT	WO 99/46593	A1	Baxter International, Inc.	09/16/1999
PCT	WO 99/46657	A2	Baxter International, Inc.	09/16/1999
PCT	WO 00/13588	A1	Beecham	03/16/2000
PCT	WO 00/21590	A1	Haemonetics Corporation	04/20/2000
PCT	WO 00/66271	A1	Bristol-Myers Squibb Company	11/09/2000
PCT	WO 01/17584	A1	Baxter International, Inc.	03/15/2001
PCT	WO 01/41832	A2	NXStage Medical, Inc.	06/14/2001
PCT	WO 01/65463	A2	Gambro, Inc.	09/07/2001
PCT	WO 01/68031	A1	P.U. Med. Konsult	09/20/2001
PCT	WO 01/78591	A1	Merck & Co., Inc.	10/25/2001

OTHER PRIOR ART OR NON-PATENT LITERATURE DOCUMENTS

(including Author (in capital letters), Title of the article, Title of the item, Date, Pages, Volume-Issue number, Publisher, City and/or Country where published.)	T
<i>Standard Specification for Transferring Clinical Observations Between Independent Computer Systems</i> , August 10, 1997, 79 pages, ASTM E 1238-97, West Conshohocken, PA, United States	
<i>Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems</i> , December 10, 1997, 15 pages, ASTM E 1394-97, West Conshohocken, PA, United States	
<i>Web site information, Global Med Announces First SAFETRACE TXTM Sale, April 1, 1999, 2 pages, Lakewood, CO, United States</i>	
<i>Web site information, Ortho-Clinical Diagnostics Signs Four-Year Sales, Marketing Agreement with Global Med Technologies, June 15, 1999, 3 pages, Raritan, NJ, United States</i>	
<i>FOSTER, BRIAN, Expert Advisory Committee on Blood Regulation Minutes, Therapeutic Products Programme, December 8, 1999, 3 pages, Health Canada</i>	
<i>VERSWEYVELD, LESLIE, Global Med Divisions Wydgate and Peoplemed Sign Hospital Contracts for Transfusion and Disease Management Services, Virtual Medical Worlds Monthly, July 18, 2001, 4 pages, Denver, CO, United States</i>	
<i>Web site information, Global Med Technologies and SIA Selected Baptist Health System for Best-of-Breed Clinical Solution, April 15, 2002, 6 pages, Wyndgate Technologies, Denver, CO, United States</i>	
<i>Web site information, Gambro BCT's Vista Software Receives FDA Market Clearance, July 25, 2002, 2 pages, Gambro, Stockholm, Sweden</i>	
<i>Web site information, Wyndgate Technologies®, SafeTrace TXTM, undated, 15 pages, United States</i>	
<i>Inservice Program Presenter's Guide, COBE Blood Component Technology, COBE SpectraTM, May 26, 1992, pages 1-236</i>	
<i>WILLIAM R. DITO et al., Bar Codes and the Clinical Laboratory: Adaptation Perspectives, Clinical Laboratory Management Review, Jan./Feb. 1992, pp. 72-85, Clinical Laboratory Management Association, Inc.</i>	
<i>ABDOO, YVONNE MARI, Designing a Patient Care Medication and Recording System That Uses Bar Code Technology, Computers in Nursing, May/June 1992, pp. 116-120, Vol. 10, No. 3</i>	
<i>Hospitals Battle Errors with Bar Codes, March 24, 2004, 3 pages, MSNBC</i>	

Please contact the undersigned attorney if the Examiner would like to discuss this communication.

Respectfully submitted,

Dated: March 23, 2005

By: 

James P. Muraff, Reg. No. 39,785
Wallenstein Wagner & Rockey, Ltd.
311 South Wacker Drive, 53rd Floor
Chicago, Illinois 60606-6630
312.554.3300
Attorneys for Applicant

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Gillian Gardner/220569